UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,014	02/01/2005	Yvonne M Yannoni	08702.0097-00	2654

60949 7590 08/03/2007

WYETH/FINNEGAN HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
08/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,014	YANNONI ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *1-11,15 and 17-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *filed 9/05 & 6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's response to supplementary restriction requirement of 2/1/2007 is acknowledged. Applicant elected Group 4C (claims 12-14 and 16) drawn to a method of use of modulators of MK2/Shc interactions, with traverse. Claims 1-11, 15, 17-61 are hereby withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues that all groups recite a complex comprising MK2. Accordingly, a search of Group 4C, in which the examiner would identify publications related to MK2 complexes, would identify MK2 complexes of other groups and as such the searches would overlap. Therefore, no serious burden of examination is imposed on the examiner if all groups recited as 4A-4D will be examined together and hence, the restriction requirement should be withdrawn.

These arguments were fully considered but were found **unpersuasive** because the inventions listed as Groups 4A-4D as mentioned previously, are directed to methods that do not share a general inventive concept, under PCT Rule 13.1, as they are utilizing products that have nothing in common in terms of structure and function. Further, the search strategy required for identifying publications which claim or disclose MK2/Shc interactions are different and separate than that required for MK2 interactions with other proteins. It may be true that the search required for the elected invention may overlap to some extent, with that required for MK2 interactions with other proteins but said search is definitely **not coextensive** with those required for Groups 4A-B and 4D and therefore, in contrast to applicant's view, rejoinder of inventions of Groups 4A-4D does impose and undue burden of searching on the examiner. Restriction is maintained and is hereby made **final.**

DETAILED ACTION

Claims 12-14 and 16 are under examination on the merits.

Claim Objections

Claim 16 is objected to because of the following informalities: said claim still recites non-elected subject matter, namely HPH2 and STS. Applicant is advised to delete said proteins from claim 16. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "MK2 polypeptide" in claim 12 (and its dependent claims 13-14) and claim 16 is indefinite. In page 12 of the disclosure applicant has defined said term as <u>including</u> variants, fragments, homologues, substitution mutants, addition mutants wherein said variants have MK2 activity. This definition is vague because for example, it is indefinite as to after how many substitutions or additions done to MK2, said polypeptide no longer has "MK2 activity". Also, is for example, 1% homologues of MK2 considered to be variants of said MK2 polypeptides. Further, the exact biological function of MK2 in vivo is unclear. Therefore, the term "MK2 activity" does not provide any additional and specific information about said variants. Furthermore, the term "including" is open language. Therefore, it is vague

as to what other proteins are considered as "MK2 polypeptides". Appropriate clarification is required.

Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "MK2 interacting protein" is indefinite. Again in page 13 of the disclosure, applicant has defined said phrase broadly in the disclosure. This phrase refers to variants of MK2 interacting proteins including substitution, deletion, addition mutants which have one or more biological activities associated with said proteins. The same questions raised above can also be raised here i.e. how many substitutions and deletions may be applied to said "MK2 interacting protein" before it loses its binding activity etc. It is further unclear as to what are the one or more biological activities of "MK2 interacting proteins". Appropriate explanation is required.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "Shc" in said claim is indefinite. Once again, in page 13 of the disclosure, applicant has defined said term to include addition, substitution mutants of src homology collagen protein (see explanation above). Also what exactly are the "motif" sequences of Shc. There is no consensus definition in the prior art for "motif" sequences. Therefore, the metes and bounds of "Shc" is unclear.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Part (a)of claim 12 (and its dependent claims 13-14) is unclear. The preamble of claim 16 is referring to screening method for compounds that both inhibit or promote complex formation, but the claim ends with only compounds that inhibit MK2/Shc interaction. Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Said claims are directed to a method of use of genera of polypeptides which are inadequately described in the disclosure.
The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. " A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that " in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula fro others and

can identify many of the species that the claims encompass. accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, applicant is claiming a method of use of a genus of "MK2 polypeptides" and a genus of "MK2 interacting polypeptides" from all sources and species, such as fish, lizards, dogs, frogs and humans, but what they do rather than what they are and this kind of definition fails to meet the requirements of 112 first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plath et al. (BBRC, 203(2), 1188-1194, 1994, cited in the IDS) in view of current kinase modulating techniques (see for example U.S. patent No. 6,420,338). Plath teaches an assay (see abstract, Figure 3 and page 1192) that detects MAKAP kinase 2 interaction with the Sh3 domain of c-abl tyrosine kinase, wherein said abl kinase can be considered to be a MAPKAP-2 kinase interacting protein. Plath also teaches that the sustrate of

MAPKAP 2 kinase, namely Hsp25 is assumed to influence actin polymerization. Plath does not teach a screening method wherein its assay method is preformed in the presence of modulator (inhibitor/activator (promoter)) compounds in order to screen for test compounds that inhibit or promote MAPKAP2 kinase interaction with c-abl tyrosine kinase.

Current kinase modulation techniques teach that once a useful kinase is identified and its substrate is known it is routine to use commonly known kinase inhibitors such as pyrazolpyrimidine or tryphostin derivatives etc. (see the above mentioned patent, column 11) or activators (promoters) such as phorbolesters in an enzyme assay in order to modulate the activity of said kinase.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the assay of Plath and add commonly known modulators of kinases to the assay mixture, according to current kinase modulation techniques.

One of ordinary skill in the art is motivated in adding kinase modulators of current assay techniques to the assay method of Plath because said methods could result in identification of agents that modulate actin polymerization leading to cell three dimensional (cytoskeleton) structure formation in vivo.

Finally, one of ordinary skill in the art has a reasonable expectation of success in adding modulators of current kinase modulation technique to the assay of Plath because such methods are merely routine in the prior art, rendering the invention obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshipouri

Maryam Monshipouri Ph.D.

Primary Examiner